

ATTORNEY DOCKET NO.: 0492611-0315 (MIT 6196)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Griffith-Cima, et al. Examiner: D. Naff
Serial No.: 09/008,945 Art Unit: 1651
Filed: January 20, 1998
For: TISSUE FORMATION BY INJECTING A CELL-POLYMERIC SOLUTION
THAT GELS IN VIVO

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

DECLARATION UNDER 37 C.F.R. 1.132

We, Anthony Atala, Linda G. Griffith, Charles A. Vacanti, and Keith T. Paige declare as follows:

1. We are the inventors of the subject matter disclosed and claimed in United States patent application Serial No.09/008,945 ('945 application) filed January 20, 1998 and entitled "TISSUE FORMATION BY INJECTING A CELL-POLYMERIC SOLUTION THAT GELS IN VIVO". This application claims priority to United States patent application Serial No. 08/056,140 now issued U.S. Patent No. 5,709,854, by Griffith-Cima et al. entitled "Tissue Formation by Injecting a Cell-Polymeric Solution that Gels In Vivo", filed on April 30, 1993.
2. This Declaration is presented for the purpose of removing from consideration by the Examiner an abstract by Atala et al., entitled "Cartilage Cells as a Potential Treatment for Reflux", American Academy of Pediatrics, 1992 Annual Meeting, Section on Urology Program for Scientific Sessions, San Francisco, CA, Saturday, October 10-12, (1992) (Reference "R"). The conference began on October 10, 1992, at which time the above-referenced abstract was available to the public in this country. The present Declaration is presented in accordance with

Ex Parte Magner, 133 USPQ 404 (CCPA 1961) and *In re Katz*, 215 USPQ 14, 18 (CCPA 1982) and establishes that the allegedly anticipatory material in Reference R was not invented by another.

3. Charles Vacanti and Anthony Atala are two of the inventors on the instant application and are also two of the co-authors of Reference R.
4. Alan B. Retik is the third co-author of Reference R. Dr. Retik is not an inventor of the claimed invention.
5. Linda G. Griffith, Charles A. Vacanti, Keith T. Paige, and Anthony Atala mutually conceived and reduced to practice the invention recited in the claims of the '945 application. Dr. Griffith has changed her name from Griffith-Cima since the parent application was filed.
6. To the extent that Reference R discloses the claimed invention, the authors of Reference R derived this subject matter from us, the inventors of the '945 application. Dr. Retik's co-authors on Reference R communicated the subject matter of the claimed invention to Dr. Retik in connection with preparing Reference R. The authors of Reference R are not the inventors of the subject matter of the '945 application.
7. All statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patents issued thereon.

Anthony Atala, M.D.

Date

Linda G. Griffith, Ph.D.

Date

Charles A. Vacanti, M.D.

Date

Keith T. Paige, M.D.

Date

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